

RUSS, AUGUST & KABAT

1 RUSS, AUGUST & KABAT  
Marc A. Fenster, State Bar No. 181067  
2 Email: mfenster@raklaw.com  
Alexander C.D. Giza, State Bar No. 212327  
3 Email: agiza@raklaw.com  
Andrew D. Weiss, State Bar No. 232974  
4 Email: aweiss@raklaw.com  
12424 Wilshire Boulevard, 12<sup>th</sup> Floor  
5 Los Angeles, California 90025  
Telephone: (310) 826-7474  
6 Facsimile: (310) 826-6991

7 Attorneys for Plaintiff  
NEUROGRAFIX

8 K&L GATES LLP  
9 David T. McDonald  
Email: david.mcdonald@klgates.com  
10 925 Fourth Avenue  
Suite 2900  
11 Seattle, WA 98104-1158  
Telephone: (206) 623-7580  
12 Facsimile: (206) 623-7022  
Attorneys for Plaintiff  
13 WASHINGTON RESEARCH FOUNDATION

14 **UNITED STATES DISTRICT COURT**  
15 **CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION**

16 NEUROGRAFIX, a California  
17 corporation; WASHINGTON  
18 RESEARCH FOUNDATION, a not-for-  
profit Washington corporation,

19 Plaintiffs,

20 vs.

21 SIEMENS MEDICAL SOLUTIONS  
22 USA, INC., a Delaware corporation; and  
23 SIEMENS AKTIENGESSELLSCHAFT,  
a German Corporation,

24 Defendants.

Case No. 10-CV-1990 MRP (RZx)

[Assigned to The Honorable Mariana  
R. Pfäelzer]

**PLAINTIFFS' OPENING CLAIM  
CONSTRUCTION BRIEF**

First Amended Complaint Filed:  
July 30, 2010

## TABLE OF CONTENTS

1	I. INTRODUCTION.....	1
2	II. BACKGROUND.....	2
3	III. APPLICABLE LEGAL PRINCIPLES. ....	4
4	IV. AGREED CLAIM TERMS. ....	5
5	V. DISPUTED CLAIM TERMS.....	5
6	A. A member of the group consisting of peripheral nerves,	
7	cranial nerves numbers three through twelve, and autonomic	
8	nerves: "Neural tissue that is outside the arachnoid space, not	
9	including cranial nerves one and two (smell and vision)." .....	5
10	B. A conspicuity of the nerve that is at least 1.1 times that of	
11	[the]/[any adjacent] non-neural tissue: "contrast (in, for	
12	example, intensity and color) between the nerve and	
13	[the]/[any adjacent] non-neural tissue is at least 1.1 times." .....	8
14	1. The proper construction of this term is dictated by the clear	
15	definition in the specification.....	8
16	2. Fact issues preclude a finding of indefiniteness. ....	9
17	C. Vector Processing: "mathematical analysis of the data set to	
18	determine direction and magnitude for a given pixel (or	
19	voxel)." .....	11
20	D. While the nerve is living in the in vivo region of the subject:	
21	"while all of the nerve tissue within the in vivo region is living	
22	(that is, not exhibiting necrosis)." .....	14
23	E. Controlling the performance of steps (a), (b), and (c) to	
24	enhance...the selectivity of said nerve: No construction	
25	necessary; or "controlling the performance of (a), (b), and (c)	
26	to enhance the ability to distinguish nerve from surrounding	
27	tissue." .....	16
28	F. Alleged Means-Plus-Function And Related Term.....	18
	1. Claims 54(c), 64: Corresponding structures are not limited	
	to performing blocks 112 through 154 in Figures 9 and 10. ....	19
	a. Claim 54(c).....	20
	(1) The corresponding structure does not require a specific	
	algorithm. ....	20
	(2) Although unnecessary to include as part of the claim	
	construction for claim 54(c), the '360 patent discloses and	
	clearly links the recited function to an algorithm - blocks	
	112 through 148 of Figures 9 and 10. ....	21
	b. Claim 64: Although unnecessary to include as part of	
	the claim construction for claim 64, the '360 patent	

**TABLE OF CONTENTS**

1	discloses and clearly links the recited function to	
2	algorithms disclosed in the specification.....	22
3	2. Claim 55(c): Corresponding structures are computer 72	
4	and front-end circuit 74 or host processing system 32 and	
5	their equivalents.....	23
6	a. Claim 55(c)(i): "vector processing said outputs to	
7	generate data representative of anisotropic diffusion	
8	exhibited by the selected structure in the region,	
9	regardless of the alignment of said diffusion-weighted	
10	gradients with respect to the orientation of said selected	
11	structure" .....	25
12	(1) The corresponding structures for claim 55(c)(i) are	
13	computer 72 and front-end circuit 74 or host processing	
14	system 32 and their equivalents. ....	25
15	(2) The corresponding structure for claim 55(c)(i) does not	
16	require a specific algorithm. ....	26
17	(3) Although not required as part of the claim construction for	
18	claim 55(c)(i), the '360 patent discloses multiple	
19	algorithms for performing claim 55(c)(i) functionality. ....	26
20	b. Claim 55(c)(ii): "processing said data representative of	
21	anisotropic diffusion to generate a data set describing	
22	the shape and position of said selected structure in the	
23	region, said data set distinguishing said selected	
24	structure from other structures in the region that do not	
25	exhibit diffusion anisotropy" .....	28
26	(1) The corresponding structures for claim 55(c)(ii) are	
27	computer 72 and front-end circuit 74 or host processing	
28	system 32 and their equivalents. ....	28
29	(2) Although not required as part of the claim construction for	
30	claim 55(c)(ii), the '360 patent discloses multiple	
31	algorithms for performing claim 55(c)(ii) functionality. ....	29
32	3. Claims 58, 61: Corresponding structures are computer 72	
33	and front-end circuit 74 or host processing system 32 and	
34	their equivalents.....	30
35	4. Claim 36(e): This term is not a step-plus-function element	
36	pursuant to Section 112 ¶6.....	33
37	5. Claims 39, 46, 49: This term is not a step-plus-function	
38	element pursuant to Section 112 ¶6.....	34
39	VI. CONCLUSION. ....	35

## TABLE OF AUTHORITIES

## CASES

<i>Acacia Media Techs. Corp. v. New Destiny Internet Group</i> , Case No. SA CV 02-1040-JW(MLGx), 2004 U.S. Dist. LEXIS 13415 (C.D. Cal. Jul. 12, 2004).....	34
<i>Arlington Industries, Inc. v. Bridgeport Fittings, Inc.</i> , Case No. 2010-1025 (Fed. Cir. Jan. 20, 2011) .....	4
<i>Biomedino, LLC v. Waters Techs. Corp.</i> , 490 F.3d 946 (Fed. Cir. 2007).....	19
<i>BJ Sys. Co. v. Halliburton Energy Sys., Inc.</i> , 338 F.3d 1368 (Fed. Cir. 2003).....	10
<i>Caluori v. One World Techs., Inc.</i> , 2010 WL 4794234 (C.D. Cal. Nov. 12, 2010) .....	10
<i>Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.</i> , 381 F.3d 1371 (Fed. Cir. 2004).....	34, 35
<i>Chimie v. PPG Indus., Inc.</i> , 402 F.3d 1371 (Fed. Cir. 2005).....	4, 13, 14
<i>Cordis Corp. v. Boston Scientific Corp.</i> , 561 F.3d 1319 (Fed. Cir. 2009).....	18
<i>Dow Chem. Co. v. Nova Chems. Corp.</i> , 629 F. Supp. 2d 397 (D. Del. 2009) .....	11
<i>Exxon Research &amp; Eng'g Co. v. U.S.</i> , 265 F.3d 1371 (Fed. Cir. 2001).....	5, 18
<i>Finisar Corp. v. DirecTV Group, Inc.</i> , 523 F.3d 1323 (Fed. Cir. 2008).....	21
<i>Green Edge Enters., LLC v. Rubber Mulch Etc., LLC</i> , 620 F.3d 1287 (Fed. Cir. 2010).....	10
<i>Hearing Components, Inc. v. Shure Inc.</i> , 600 F.3d 1357 (Fed. Cir. 2010).....	5
<i>In re Dossel</i> , 115 F.3d 942 (Fed. Cir. 1997).....	20, 21, 22, 26
<i>Intergraph Hardware Techs. Co. v. Toshiba Corp.</i> , 508 F. Supp. 2d 752 (N.D. Cal. 2007).....	10
<i>Int'l Dev. LLC v. Richmond</i> , 2010 WL 4703779 (D.N.J. Nov. 12, 2010) .....	11
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995).....	9
<i>Masco Corp. v. U.S.</i> , 303 F.3d 1316 (Fed. Cir. 2002).....	33, 34, 35

## TABLE OF AUTHORITIES

1	<i>Med. Instrumentation &amp; Diagnostics Corp. v. Elekta AB</i> ,	19
2	344 F.3d 1205 (Fed. Cir. 2003).....	
3	<i>Miles Lab. v. Shandon, Inc.</i> ,	5, 18
4	997 F.2d 870 (Fed. Cir. 1993).....	
5	<i>O.I. Corp. v. Tekmar Co.</i> ,	34, 35
6	115 F.3d 1576 (Fed. Cir. 1997).....	
7	<i>Phillips v. AWH Corp.</i> ,	4, 13
8	415 F.3d 1303 (Fed. Cir. 2005).....	
9	<i>Spancion, Inc. v. Int’l Trade Comm’n</i> ,	10
10	– F.3d –, 2010 WL 5156992 (Fed. Cir. Dec. 21, 2010) .....	
11	<i>Tech. Licensing Corp. v. Videotek, Inc.</i> ,	10
12	545 F.3d 1316 (Fed. Cir. 2008).....	
13	<i>Teleflex, Inc. v. Ficosa N. Am. Corp.</i> ,	4, 13, 14
14	299 F.3d 1313 (Fed. Cir. 2002).....	
15	<i>Vitronics Corp. v. Conceptronic, Inc.</i> ,	4
16	90 F.3d 1576 (Fed. Cir. 1996).....	
17	<i>Young v. Lumenis, Inc.</i> ,	5
18	492 F. 3d 1336 (Fed. Cir. 2007).....	
19	<b>STATUTES</b>	
20	35 U.S.C. § 112 ¶2	20
21	35 U.S.C. § 112 ¶6	33, 34, 35

1 Plaintiffs NeuroGrafix and Washington Research Foundation (collectively,  
2 "NeuroGrafix") move this Court for an order construing certain claim terms from  
3 the asserted claims<sup>1</sup> of U.S. Patent No. 5,560,360 (the "'360 patent") (Weiss Decl.<sup>2</sup>  
4 Ex. A).

5 **I. INTRODUCTION.**

6 This is a case involving a major advance in medical imaging that has  
7 become widely used to identify and diagnose issues with neural tissue. In  
8 particular, the invention of the '360 patent involves using a Magnetic Resonance  
9 Imaging (MRI) machine to reliably image nerves such that the nerve is at least  
10 10% brighter than the surrounding tissue (and therefore readily identifiable in an  
11 MRI image). Prior to this invention, doctors did not know how to use MRI to non-  
12 invasively and reliably visualize peripheral nerves (generally neural tissue outside  
13 the arachnoid space), which often run parallel with other directional tissues, such  
14 as lymphatics, fat, muscle and blood vessels and are typically surrounded by fatty  
15 tissues. The inventors of the '360 patent invented a way to use MRI to reliably  
16 visualize peripheral nerves without resorting to the use of invasive contrast agents  
17 that had to be injected into the body. A second aspect of the invention of the '360  
18 patent uses information obtained by applying electromagnetic pulses and so-called  
19 diffusion gradients to calculate vectors showing the direction of anisotropy (the  
20 effective direction of water flow at a particular point, which generally corresponds  
21 to the orientation of the nerve or other neural tissue) for each pixel or voxel, and  
22 then to connect the vectors together to show the shape and position of the neural  
23 tissue in three dimensions, including neural tracts as in the brain and spinal cord.  
24 Weiss Decl. Ex. B (exemplary image).

25 These techniques have literally revolutionized neuroradiology, allowing  
26 doctors to non-invasively diagnose a variety of neurological disorders that were not

27 <sup>1</sup> Plaintiffs are presently asserting claims 1, 3–7, 11–13, 18–20, 22–26, 28, 35–37,  
28 39–44, 46–47, 49–50, 54–56, 58–59, and 61–66 against Defendants.

<sup>2</sup> "Weiss Decl." refers to the Declaration of Andrew D. Weiss in Support of  
Plaintiffs' Opening Claim Construction Brief, filed concurrently herewith.

1 detectable by medical imaging in the past and to better treat a wide variety of  
2 disorders during surgery by helping doctors guide surgical instruments to avoid  
3 damaging healthy neural tissue.

## 4 **II. BACKGROUND.**

5 As a graduate student doing research in an MD-PhD course of study, Dr.  
6 Aaron Filler, one of the co-inventors, began researching techniques for imaging  
7 neural tissue at Harvard University in 1978. During the following 12 years, he  
8 developed contrast agent-based methods for medical imaging of neural tissues, but  
9 in 1991, realized that a method not requiring contrast agents might be feasible.  
10 Prior to the invention, there was no way to reliably image nerves outside of the  
11 arachnoid space (*i.e.*, outside of the brain and spinal cord) without contrast agents,  
12 such that it could be used to diagnose patients. This is generally because doctors  
13 did not have a way to reliably differentiate neural tissue from the tissues that  
14 surround the nerves outside of the arachnoid space, such as fat, muscle and blood  
15 vessels.<sup>3</sup>

16 A brief introduction to MRI and how it works is provided at ¶¶ 24 to 55 of  
17 the Filler report.<sup>4</sup> Generally, one can control the MRI machine to apply different  
18 sequences and combinations of excitation pulses ("pulse sequences") to cause  
19 different effects and visualize different tissues or attributes of tissues.

20 The inventors, led by Dr. Filler, discovered that it was possible to identify  
21 and follow any axonal neural tract in any part of the body where none of these  
22 structures could be imaged reliably anywhere in the body before the invention. For  
23 example, as discussed in the patent, the inventors were the first to discover that  
24 using a fat suppression pulse sequence in combination with diffusion-weighted  
25

26 <sup>3</sup> Neural tissue exiting the brain and spinal cord as nerve roots was relatively easy  
27 to visualize with MRI because it is surrounded only by spinal fluid. Bulk white  
28 matter of the brain could also be visualized because it is surrounded by uniform  
gray matter. It should be noted that, at the time, the various internal neural tract  
constituents could not be distinguished and visualized.

<sup>4</sup> The Filler report is attached as Exhibit C to the Weiss Decl.

1 gradients<sup>5</sup> produced a synergistic effect that enhanced the ability to image  
2 peripheral nerves. *See* '360 patent at 22:28-23:26. Indeed, at the time of the  
3 invention, it was generally believed that fat suppression was not helpful in the  
4 process of imaging nerves. *See id.* at 12:35-40. The inventors further found that  
5 other pulse sequences, such as vessel suppression, also helped to enhance the nerve  
6 in an MRI data set. The result of using these pulse sequences is that the nerve  
7 becomes much more conspicuous when compared to the surrounding tissue.

8 In addition to increasing the conspicuity of the nerve, the inventors also  
9 discovered that vector processing techniques could be used on the diffusion  
10 anisotropy data to discover the shape and position of neural tissue by determining  
11 its orientation within each image pixel or voxel. In particular, the inventors  
12 discovered how to apply vector processing techniques on data sets from the  
13 invention to generate a direction and magnitude of diffusion for each voxel (or  
14 pixel). Using known techniques for connecting vectors, the inventors figured out  
15 how to create three-dimensional data sets representative of neural tissue, such as  
16 those shown in Figures 16 and 17 of the '360 patent, two of the very first  
17 tractographic images ever made. The disclosed three-dimensional imaging  
18 technique has been the subject of over 6,000 peer reviewed medical science  
19 publications in the past five years and is the subject of a new \$50 million "Human  
20 Connectome Project" launched by the National Institutes of Health in 2010 to  
21 commence mapping every neural connection in the human brain.

22 In 1998, Dr. Filler and a group of others formed NeuroGrafix to put the  
23 inventions to use helping patients. NeuroGrafix obtained an exclusive license to  
24 the '360 patent from Washington Research Foundation, which was the exclusive  
25 licensee of the '360 patent from its owner, the University of Washington.

26 <sup>5</sup> Using diffusion-weighted gradients is a technique known at the time of the  
27 invention for imaging anisotropic structures and suppressing isotropic structures.  
28 Water is said to be anisotropic when it tends to diffuse preferentially in a particular  
direction. Conversely, water is said to be isotropic if it diffuses in all directions  
approximately equally. Tissues such as nerves, neural tracts and muscles contain  
water that exhibits anisotropic diffusion.

1 NeuroGrafix, through its field of use sublicensees, has been successfully practicing  
2 the revolutionary imaging technology disclosed in the '360 patent, helping  
3 thousands of patients.

4 The patented technology is also now being offered as standard packages by  
5 MRI manufacturers, such as Siemens, and practiced by imaging facilities, clinics  
6 and hospitals across the country and around the world.

### 7 **III. APPLICABLE LEGAL PRINCIPLES.**

8 While the Court is familiar with the law of claim construction, NeuroGrafix  
9 summarizes for the Court the primary legal principles that are relevant to claim  
10 construction in this matter. First, "it is well settled that, in interpreting an asserted  
11 claim, the court should look first to the intrinsic evidence of record, i.e. the patent  
12 itself, including the claims, the specification, and, if in evidence, the prosecution  
13 history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir.  
14 1996). Second, the danger of reading limitations from the specific embodiments  
15 described in the specification must be avoided. *Phillips v. AWH Corp.*, 415 F.3d  
16 1303, 1319-20 (Fed. Cir. 2005). Third, the claims should not be construed to  
17 exclude a preferred embodiment. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371,  
18 1377 (Fed. Cir. 2005).

19 Finally, claim terms should be construed in accordance with their ordinary  
20 and customary meaning, as a person of ordinary skill in the art would understand  
21 them at the time of the invention. *Phillips*, 415 F.3d at 1312-13. A construction  
22 may depart from the ordinary and customary meaning only if there is a clear and  
23 unambiguous disavowal of claim scope. *Arlington Industries, Inc. v. Bridgeport*  
24 *Fittings, Inc.*, Case No. 2010-1025, slip op. at 12 (Fed. Cir. Jan. 20, 2011);  
25 *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002);  
26 *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005).

27 The definiteness analysis requires a determination of "whether one skilled in  
28 the art would understand the bounds of the claim when read in light of the

RUSS, AUGUST & KABAT

specification." *Miles Lab. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). A claim is definite as long as it is not "insolubly ambiguous," even if the task of construing the term is "formidable." *See, e.g., Exxon Research & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). A claim is also definite even if reasonable persons disagree regarding the construction. *Id.* Defendants bear the heavy burden of showing that a term is indefinite by clear and convincing evidence. *See, e.g., Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1366 (Fed. Cir. 2010) (reversing the district court's judgment of invalidity for indefiniteness); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1345 (Fed. Cir. 2007) (reversing the district court's judgment of invalidity for indefiniteness).

#### IV. AGREED CLAIM TERMS.

The constructions agreed on by the parties can be found on pages 14-16 of the exhibit to the Joint Claim Construction and Prehearing Statement (Weiss Decl. Ex. E).

#### V. DISPUTED CLAIM TERMS.

NeuroGrafix's proposed constructions are based on the intrinsic evidence when viewed by one having ordinary skill in the art. Defendants, on the other hand, have proposed constructions that contradict the intrinsic evidence and the doctrines of claim construction.

Pursuant to the Court's Order, NeuroGrafix will brief only the top 10 disputed terms included in the Joint Claim Construction and Prehearing Statement.

- A. **A member of the group consisting of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves:<sup>6</sup> "Neural tissue that is outside the arachnoid space, not including cranial nerves one and two (smell and vision)."**

NeuroGrafix's Construction	Defendants' Construction
Neural tissue that is outside the arachnoid space, not including cranial nerves one and two (smell and vision). Commonly referred to as the peripheral nervous system, as opposed to the central nervous system.	A nerve that is listed in Taber's Cyclopedic Medical Dictionary (17th ed. 1989) on pages 182, 463 (excluding cranial nerves 1 and 2), 1290, or 1291 and/or that is otherwise not part of the central nervous system.

<sup>6</sup> This term can be found in claims 1, 3, 7, 11, 12, 18, 63 and 66.

1 NeuroGrafix's proposed construction of this term should be adopted because  
2 it is consistent with the explicit definition provided by the applicants in the file  
3 history, which is exactly congruent with the universally accepted anatomical  
4 definition of the boundaries of the "peripheral nervous system" as opposed to the  
5 "central nervous system."

6 The inventors' statements in the file history clearly and unmistakably show  
7 that they intended this phrase to mean the "peripheral nervous system," which is  
8 neural tissue outside the arachnoid space. The applicants stated:

9 [A]pplicants' invention is directed to neural imaging in body regions that  
10 include bone, muscle, lymphatics, tendons, ligaments, intermuscular septa,  
11 as well as collections of fatty tissues, air and fluid spaces, veins, arteries,  
12 joints, skin, mucus membranes, and other tissues. That is, applicants  
13 recognize that prior art MRI techniques allow the observation of neural  
14 tissue that is within the arachnoid space. ***That is exactly why rejected Claim***  
15 ***89 was drafted to limit the invention to nerves that are "a member of the***  
16 ***group consisting of peripheral nerves, cranial nerves numbers three***  
17 ***through twelve, and autonomic nerves."*** Stated differently, but in a  
18 congruent manner, Claim 89 was drafted to intentionally exclude  
19 interpretation that would extend claim coverage to prior art methods and  
20 apparatus that: (1) are capable of imaging cranial nerves I (smell) and II  
21 (vision), which are actually an extension of the central nervous system with  
22 arachnoid, cerebrospinal fluid and dura mater; but (2) are not capable of  
23 imaging the recited peripheral nerves, cranial nerves three through twelve, or  
24 autonomic nerves ***that pass outside the arachnoid space (i.e., into the***  
25 ***peripheral nervous system).***

26 Weiss Decl. Ex. H at 7-8.<sup>7</sup> Thus, the intrinsic record makes it crystal clear that

27 <sup>7</sup> See also, *id.* at 9 (The inventors further distinguish the Hajnal et al. prior art  
28 because it "does not disclose or suggest MRI-based imaging of nerves that  
achieves a conspicuity greater than 1.1 for nerves that are outside the arachnoid  
space.").

1 this language means neural tissue outside the arachnoid space (*i.e.*, the peripheral  
2 nervous system).<sup>8</sup>

3 This construction is also supported by and consistent with the specification.  
4 The specification refers to peripheral, autonomic and cranial nerves "commonly  
5 travel[ing] through and along bone, muscle, lymphatics, tendons," and other tissues  
6 that a person of ordinary skill knows would only be found outside of the arachnoid  
7 space. *See* '360 patent at 1:31-37; *see also id.* at 5:60-65 (noting that fat, which is  
8 not contained within the arachnoid space, "impairs the imaging of peripheral  
9 nerves"); 5:3-39 (disclosing the existence of prior art for imaging "non-peripheral,  
10 white matter nerve tracts in the brain," which are inside of the arachnoid space).  
11 Thus, NeuroGrafix's proposed construction reflects how a person having ordinary  
12 skill in the art would understand this term in light of the intrinsic evidence.

13 It is not clear to NeuroGrafix if Defendants' construction is meant to  
14 encompass parts of the central nervous system. To the extent Defendants'  
15 construction means to exclude parts of the central nervous system, the parties'  
16 competing definitions may not be fundamentally different. In that case, the Court  
17 should adopt NeuroGrafix's definition because it is clearer and directly supported  
18 by the intrinsic record.

19 If Defendants' construction is not meant to exclude parts of the central  
20 nervous system, it should be rejected because it contradicts the intrinsic evidence.  
21 Defendants' proposed construction could be interpreted as broadening the term to  
22 include all peripheral, autonomic and cranial nerves regardless of whether they are  
23 inside of the arachnoid space. Page 182 of Taber's Cyclopedic Medical Dictionary,  
24 for example, lists nerves that are connected to the brain and spinal cord and thus at

25 <sup>8</sup> A person with ordinary skill in the art knows that the arachnoid space refers to the  
26 tissues within the arachnoid mater. The arachnoid mater is a membrane that covers  
27 the cerebro spinal fluid, the nerve roots, the brain and spinal cord. The arachnoid  
28 space of the CNS transitions into the perineurium that lines the fascicles of the  
peripheral nervous system at the Obersteiner-Redlich zone. This zone defines the  
formal anatomic transition line between central nervous system tissues (with  
oligodendroglial supporting cells) and peripheral nervous system tissues (with  
Schwann cells as supporting elements).

1 least a portion of the listed nerves are inside of the arachnoid space. *E.g.*, Weiss  
2 Decl. Ex. I at SMSAG0051250. As explained above, the inclusion of nerves inside  
3 of the arachnoid space contradicts the clear and unambiguous intent of the  
4 inventors expressed in the file history. Weiss Decl. Ex. H at 7-8, 9. Additionally,  
5 the list of nerves included in Taber's Cyclopedic Medical Dictionary does not even  
6 appear to be complete. For example, a person having ordinary skill in the art  
7 would know that many clinically significant nerves are missing, such as the  
8 obturator internus nerve, superior gluteal nerve and many smaller named nerves  
9 including clinically significant nerves that are too small to have names.

10 For the foregoing reasons, the Court should adopt NeuroGrafix's proposed  
11 construction and reject Defendants' proposed construction.

12 **B. A conspicuity of the nerve that is at least 1.1 times that of**  
13 **[the]/[any adjacent] non-neural tissue: "contrast (in, for**  
14 **example, intensity and color) between the nerve and [the]/[any**  
15 **adjacent] non-neural tissue is at least 1.1 times."**

14 <b>NeuroGrafix's Construction</b>	<b>Defendants' Construction</b>
15 Contrast (in, for example, intensity 16 and color) between the nerve and [the]/[any adjacent] non-neural tissue is at least 1.1 times	Term not amenable to construction

17 Contrary to Defendants' position, not only is this term amenable to  
18 construction, but it is expressly defined in the specification.

19 **1. The proper construction of this term is dictated by the clear**  
20 **definition in the specification.**

21 The specification expressly defines conspicuity as "contrast (in, for example,  
22 intensity or color) between the nerve and the image background":

23 These neurograms exhibit a high nerve conspicuity, *which for the purpose*  
24 *of the ensuing discussion will be understood to refer to the contrast (in, for*  
25 *example, intensity or color) between the nerve and image background.*

26 Weiss Decl. Ex. A at 11:56-59 (emphasis added). Thus, the specification defines  
27 exactly what is meant by conspicuity. It is a fundamental tenet of claim

28 <sup>9</sup> This term can be found in asserted claims 1, 3, 7, 11, 12 and 18.

RUSS, AUGUST & KABAT

1 construction law that where, as here, the patentee defines the term in the  
2 specification, that definition is the proper construction of the term. *E.g., Markman*  
3 *v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) ("As we have  
4 often stated, a patentee is free to be his own lexicographer."). This definition is  
5 also repeated in the file history. Weiss Decl. Ex. K at 11 ("The nerve 'conspicuity'  
6 refers to the contrast (in, for example, the intensity or color) between the nerve and  
7 the image background.").

8 The plain meaning of the phrase, incorporating the express definition of  
9 conspicuity from the intrinsic evidence, is that "a conspicuity of the nerve that is at  
10 least 1.1 times that of [the]/[any adjacent] non-neural tissue" means the "contrast  
11 (in, for example, intensity and color) between the nerve and [the]/[any adjacent]  
12 non-neural tissue is at least 1.1 times." This is how one of skill in the art would  
13 understand the term in light of the clear intrinsic evidence. Both Dr. Filler and Dr.  
14 Moseley, Defendants' expert, testified that one of skill in the art would understand  
15 the claim language to require that the signal intensity of the nerve must be at least  
16 10% greater than the signal of the surrounding non-neural tissue. *See* Weiss Decl.  
17 Ex. L at ¶ 27 (rebuttal expert report of Dr. Filler); Weiss Decl. Ex. M at 55:10-15,  
18 58:12-19 (Dr. Moseley agreeing that "the conspicuity must be at least 1.1 means  
19 that the comparison must show that the nerve measurable is at least 10 percent  
20 greater than the non-nerve measurable"). Thus, because the meaning of the term is  
21 clear from the claim language and the specification, the proper construction of this  
22 term is as proposed by NeuroGrafix.

## 23 2. Fact issues preclude a finding of indefiniteness.

24 Defendants apparently argue that even though the specification makes clear  
25 that "conspicuity" means contrast and even though both Dr. Filler and Dr. Moseley  
26 agree that one having skill in the art would understand this to mean that the neural  
27 tissue is at least 10% brighter than the non-neural tissue, that the claim term is  
28 nonetheless indefinite.

Whether the claim is indefinite is a "question[] of law with underlying factual determinations." *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1298-99 (Fed. Cir. 2010); *see also BJ Svs. Co. v. Halliburton Energy Svs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) ("Like enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature."). To prove indefiniteness, Defendants must prove by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as the artisan's knowledge of the relevant art area. *Spansion, Inc. v. Int'l Trade Comm'n*, – F.3d –, 2010 WL 5156992, \*7 (Fed. Cir. Dec. 21, 2010) ; *BJ Svs. Co.*, 338 F.3d at 1372; *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

Here, even if Defendants' expert report were sufficient to make out a prima facie case of indefiniteness – which it is not – there is, at a minimum, substantial issues of fact that preclude a determination of indefiniteness. For instance, the parties apparently disagree as to whether one of skill would be able to discern the boundaries of the claim (in other words, whether one of skill would be able to discern what it means for neural tissue to be at least 10% brighter than non-neural tissue). *See* Weiss Decl. Ex. L at ¶¶ 25-35 (opining that a person having ordinary skill in the art would understand the bounds of the term).

Where indefiniteness turns on an issue of fact, however, determining whether a term is indefinite is properly left for the jury. *BJ Svs. Co.*, 338 F.3d at 1372 ("definiteness...is amenable to resolution by jury where the issues are factual in nature."); *see also Caluori v. One World Techs., Inc.*, 2010 WL 4794234, \*9 n.8 (C.D. Cal. Nov. 12, 2010) ("[w]hile the Court declines to resolve the issue at this stage, it appears that the claim allows for one skilled in the art to understand the bounds of the claim")); *Intergraph Hardware Techs. Co. v. Toshiba Corp.*, 508 F. Supp. 2d 752, 773 n.3 (N.D. Cal. 2007) (holding that "indefiniteness argument

[was] inappropriate at the claim construction stage"); *Dow Chem. Co. v. Nova Chems. Corp.*, 629 F. Supp. 2d 397, 404, 407 (D. Del. 2009) (construing disputed claim term and holding that indefiniteness was a question for the jury); *Int'l Dev. LLC v. Richmond*, 2010 WL 4703779, at \*7 (D.N.J. Nov. 12, 2010) ("the Court will not entertain the indefiniteness argument [before the close of all discovery] and will construe the term because it is 'amenable to construction, however difficult that task may be[.]'").

Accordingly, the Court should adopt NeuroGrafix's fully supported construction and should reject Defendants' assertion that the claim is invalid.

**C. Vector Processing:<sup>10</sup> "mathematical analysis of the data set to determine direction and magnitude for a given pixel (or voxel)."**

NeuroGrafix's Construction	Defendants' Construction
Mathematical analysis of the data set to determine direction and magnitude for a given pixel (or voxel)	Calculating the ratio of $D_{pl}/D_{pr}$ or calculating data according to equation 3, 4, 5, and/or 6.

The meaning of "vector processing" is clear from the claim language and the specification. A vector is the representation of data as a magnitude and a direction. Defendants apparently do not dispute this. In fact, the parties agree that an "effective *vector*" should be construed as "*direction and magnitude* that represents the data at a given point (or voxel)." Weiss Decl. Ex. E at Exhibit at 14 (emphasis added). Combined with the term "processing" in the context of the intrinsic record, "vector processing" simply refers to a mathematical analysis of the data set to determine direction and magnitude for a given pixel (or voxel).

Indeed, the claims all use "vector processing" consistently to require "vector processing" the outputs for the diffusion-weighted gradients in order "to generate data representative of anisotropic diffusion."<sup>11</sup> (Anisotropic diffusion is also an agreed term, and refers to greater water mobility in some directions compared to others. Weiss Decl. Ex. E at Exhibit at 14.) In other words, "vector processing" involves analyzing data from diffusion-weighted gradients to determine the

<sup>10</sup> This term can be found in asserted claims 11, 22, 36 and 55.

<sup>11</sup> See Claims 11, 22, 36 and 55.

1 direction and magnitude of anisotropic diffusion at a particular point (or voxel) in  
2 neural tissue. For example, one embodiment of the data representative of  
3 anisotropic diffusion claimed in the dependent claims is that it must include an  
4 "effective vector." *See, e.g., '360 patent at claim 41* ("wherein said data  
5 representative of anisotropic diffusion include a description of an effective vector  
6 representative of the anisotropic diffusion exhibited by said neural tissue"). Thus,  
7 the plain meaning of this term, in the context of the claim language, is that "vector  
8 processing" refers to processing the outputs of the diffusion weighted gradients to  
9 generate a vector that represents a magnitude and the direction of anisotropic  
10 diffusion at a particular pixel (or voxel).

11 This is completely consistent with the specification. The specification  
12 teaches, in the section entitled "Vector Processing and Three-Dimensional Image  
13 Generation," that vector processing is for observing diffusional anisotropy  
14 "involv[ing] the *combination of information from anisotropy measurements*  
15 obtained along three standard orthogonal axes or using information from multiple  
16 fixed axes." '360 patent at 20:29-32 (emphasis added). The specification further  
17 teaches:

18 For each pixel in the image to be produced, information concerning the  
19 corresponding pixels in the four diffusion gradients images is combined to  
20 produce a diffusion vector, representative of water molecule movement  
21 along the nerve fiber in either direction. *This vector has a magnitude*  
22 *representative of the image intensity of the pixel and a direction*  
23 *representative of an "effective" diffusion gradient associated with the pixel.*  
24 '360 patent at 20:38-45 (emphasis added).

25 Moreover, while the specification identifies particular equations that can be  
26 used to mathematically analyze diffusion-weighted gradients to determine the  
27 vectors (*see '360 patent at 20:47-21:5*), there is no clear and unmistakable  
28 disclaimer of vector processing encompassing other possible equations. *See, e.g.,*

1 *Teleflex*, 299 F.3d at 1324. There is also nothing in the intrinsic evidence  
2 preventing vector processing from also resulting in more than one vector, such as  
3 where two neural tracts cross each other in a cross section being imaged. Because  
4 it is fully supported by the intrinsic record, NeuroGrafix's construction should  
5 therefore be adopted.

6 Defendants' strained construction should be rejected because it is  
7 inconsistent with the intrinsic evidence. The concept of vector processing was  
8 well-known in the field of mathematics at the time of the invention as a particular  
9 type of mathematical processing. The specification does not limit vector  
10 processing to the particular type of vector processing used in the preferred  
11 embodiment. Instead, it discloses a number of embodiments of vector processing,  
12 including multiple forms of vector analysis, "tensor analyses employing tensors of  
13 various ranks" and other alternatives used in evaluating magnetic, thermal and  
14 structural anisotropy data. '360 patent at 20:47-21:47. Defendants' construction is  
15 improper because it is both inconsistent with the specification and importing  
16 limitations from the specification. *See Phillips*, 415 F.3d at 1319-20; *Chimie*, 402  
17 F.3d at 1377.

18 The first portion of Defendants' construction must be rejected as  
19 contradictory to the intrinsic evidence. The ratio of  $D_{pl}$  to  $D_{pr}$  is obtained to  
20 determine how to orient the diffusion-weighted gradients. '360 patent at 19:62-  
21 20:5. It is not part of vector processing. Rather, it is done to determine what  
22 diffusion-weighted gradients to apply. *Id.* The claims require that vector  
23 processing be performed on the outputs from a "predetermined arrangement of  
24 diffusion-weighted gradients." *See, e.g.*, '360 patent at claims 11, 36. Thus, the  
25 gradients necessarily must have been chosen and applied before vector processing  
26 is done. Vector processing cannot therefore, include the selection of which  
27 diffusion gradients to apply, as is represented by the ratio of  $D_{pl}$  to  $D_{pr}$ . Thus, the  
28 Court should not construe this term to include calculating the ratio of  $D_{pl}$  to  $D_{pr}$ .

RUSS, AUGUST & KABAT

The last portion of Defendants' construction limiting vector processing to using equations (3), (4), (5) and/or (6) from the specification must also be rejected because it is an improper attempt to import limitations from the specification into the claims. The specification expressly describes additional embodiments, including the vector analysis disclosed in Bassier et al., *Fiber Orientation Mapping in an Anisotropic Medium with NMR Diffusion Spectroscopy*, SMRM BOOK OF ABSTRACTS 1221 (1992), "tensor analysis employing tensors of various ranks," and other well-known techniques used "in the evaluation of magnetic, thermal, and structural anisotropy data." '360 patent at 21:35-22:5. Limiting vector processing as proposed by Defendants excludes these embodiments and improperly limits the appropriate breadth of the term. *Chimie*, 402 F.3d at 1377.

Furthermore, equations (3), (4), (5) and (6) are limited to the preferred embodiment that used only three orthogonal gradients (the x-, y- and z-orthogonal directions). '360 patent at 20:36-39. The embodiment is merely an example ('360 patent at 20:36-37) and there is nothing in the intrinsic evidence excluding the use of more gradients. *See* '360 patent at 20:5-8 (referencing the possible use of "an infinite variety of differently oriented gradients"). It is improper to import limitations from preferred embodiments without an express and unambiguous disclaimer of claim scope. *See, e.g., Teleflex*, 299 F.3d at 1324.

For the foregoing reasons, the Court should adopt NeuroGrafix's proposed construction and should reject Defendants' proposal.

**D. While the nerve is living in the in vivo region of the subject:<sup>12</sup>  
"while all of the nerve tissue within the in vivo region is living  
(that is, not exhibiting necrosis)."**

NeuroGrafix's Construction	Defendants' Construction
While all of the nerve tissue within the in vivo region is living (that is, not exhibiting necrosis)	Siemens contends this phrase does not require construction and should be understood from its ordinary meaning. To the extent it is construed, Siemens contends it should be construed to mean "while some part of the nerve within the in vivo region of the subject

<sup>12</sup> This term can be found in asserted claims 1, 3, 7, 11, 12 and 18.

is alive (that is, not dead)."

The parties agree that the plain and ordinary meaning of this term should apply. The term needs construction, however, because the parties disagree with the proper formulation of the ordinary meaning.

Only NeuroGrafix's proposed construction, however, is consistent with the plain and ordinary meaning of the term. The *in vivo* region referred to by this term is the region exposed to the various fields (*e.g.*, magnetic polarizing field, excitation field, etc.) recited in the claims. *See, e.g.*, '360 patent at claim 1(a), (b), (c). The plain language of the term, therefore, requires that all of the nerve tissue being imaged in the *in vivo* region be alive, which means it is not exhibiting necrosis. Weiss Decl. Ex. F at N-8 (defining necrosis as "[d]eath of areas of tissue or bone surrounded by healthy parts"). NeuroGrafix's construction is consistent with the ordinary meaning in light of the intrinsic evidence and should be adopted.

Instead of adopting the ordinary meaning, Defendants' proposed construction redrafts the term in an apparent attempt to incorporate prior art. Defendants' proposed construction simply seeks to add broadening language to the term ("while *some part of* the nerve is living") in order to bolster their invalidity argument. The ordinary meaning of "while the nerve is living" is not consistent with only some part of the nerve being alive and there is no support in the intrinsic evidence that the inventors intended for the term to be broader than its ordinary meaning. Furthermore, a person having ordinary skill in the art at the time knew that it was possible to image the dead portions of nerves due to the different characteristics of a dead nerve and a live nerve. Weiss Decl. Ex. G (article describing imaging nerves exhibiting Wallerian degeneration, which occurs in the portion of a nerve that is cut or crushed and no longer alive; noting at 742 that "[i]n the untraumatized leg, the normal tibial nerve cannot be identified"). Defendants' proposed construction improperly broadens this term such that the very prior art this term was included to distinguish is converted back into potentially invalidating prior art. The Court should therefore adopt NeuroGrafix's proposed construction.

E. Controlling the performance of steps (a), (b), and (c) to enhance...the selectivity of said nerve<sup>13</sup>: No construction necessary; or "controlling the performance of (a), (b), and (c) to enhance the ability to distinguish nerve from surrounding tissue."

NeuroGrafix's Construction	Defendants' Construction
No construction necessary; or "controlling the performance of (a), (b), and (c) to enhance the ability to distinguish nerve from surrounding tissue"	Term not amenable to construction

This term needs no construction because it is common, ordinary language and should be given its common ordinary meaning. The plain meaning of controlling is clear: exercising control over. Similarly, there can be no real dispute as to what it means to enhance the selectivity of the nerve. Enhance means to improve, and there is no dispute about the meaning of "selectivity".<sup>14</sup> There is nothing ambiguous or indefinite about enhancing the selectivity of (*i.e.*, the ability to distinguish) a nerve.

Step (a) refers to applying the magnetizing polarizing field, step (b) refers to applying the excitation field, and step (c) refers to sensing the output of the resonance field. *E.g.*, '360 patent at claim 1. Thus, the plain meaning of the claim term is controlling the performance of the magnetic polarizing field and the excitation field and the sensing of the resonance field in a manner that enhances the ability to distinguish nerve from surrounding tissue.

In practical terms, both the claims and the specification make clear that controlling steps (a), (b) and (c) refers to the affirmative act of applying one or more pulse sequences and configurations to control the output received from an MRI machine.<sup>15</sup> *See, e.g.*, '360 patent at 6:34-45 ("Previously, however, no simple

<sup>13</sup> This term can be found in asserted claims 1, 3, 7, 11, 12 and 18.

<sup>14</sup> Indeed, Defendants originally proposed "selectivity" as a term to be construed, and proposed that it be construed as the "degree to which one can discriminate or discern." Weiss Decl. Ex. J at Exhibit at 5. During the meet and confer process, after NeuroGrafix agreed with Defendants' proposed construction, Defendants withdrew their request to have it construed.

<sup>15</sup> A pulse sequence is the MRI equivalent to computer source code telling a computer how to run a program. A pulse sequence controls how the various magnets and other hardware in an MRI machine are used to generate an output. In particular, a computer hooked to the MRI machine uses the pulse sequence to

(single) or complex (double or multiple) pulse sequence has been able to increase the relative signal intensity of nerve"). Furthermore, the dependent claims give examples of what it means to control steps (a), (b), and (c) to enhance the selectivity of the nerve that confirm this common, ordinary meaning:

- "wherein step (d) [the controlling step at issue] includes the step of selecting a combination of echo time and repetition time that exploits a characteristic spin-spin relaxation coefficient of peripheral nerves...." '360 patent at claim 25;
- "wherein step (d) includes the step of controlling said step (b) to expose the in vivo region to an excitation field that induces a magnetization transfer from non-anisotropically diffusing water in the in vivo region to anisotropically diffusing water in said nerve, to more readily distinguish the nerve from non-neural tissue." '360 patent at claim 26;
- "wherein...said step (d) suppresses the blood vessels from the data set" '360 patent at claim 28; and
- "wherein...said step (d) includes the step of selecting the polarizing field of step (a) and the excitation field of step (b) to suppress the blood vessels and the cerebrospinal fluid from said data set." '360 patent at claim 30.

The specification provides many examples and combinations of ways to control steps (a), (b) and (c) to enhance the selectivity of the nerve. An exemplary pulse sequence is shown in Figure 11 of the '360 patent. The specification is also very broad in describing the types of pulse sequences that can be used to enhance the selectivity of a nerve, including but not limited to using fat suppression sequences, vessel suppression sequences, T2-weighting sequences, magnetization transfer, diffusion weighting, echo planar, etc. *See, e.g.*, '360 patent at 9:66-10:7,

determine the sequence of control signals that cause precisely timed and synchronized activations of the various magnetic field polarizing, radiofrequency exciting, and radiofrequency sensing subsystems to which the computer is connected and whose operation it directly controls.

12:21-31. Therefore, the Court need not construe this term but, if the Court feels a construction is necessary, it should adopt NeuroGrafix's proposed construction.

Defendants refuse to offer a construction on the basis that this term is indefinite because it is not amenable to construction. As described above, however, the plain meaning is abundantly clear. Certainly a person having ordinary skill in the art would understand that this term is met when the operator controls specified parts of the MRI machine to increase the ability to distinguish the nerve in the output, many examples of which are included in the claims and intrinsic evidence.<sup>16</sup> This term is therefore not "insolubly ambiguous" and Defendants' argument should be rejected. *See, e.g., Exxon Research*, 265 F.3d at 1375; *Miles Lab.*, 997 F.2d at 875.

#### **F. Alleged Means-Plus-Function And Related Term.**

Independent claims 54 and 55 are both apparatus claims written in means-plus-function form. Despite 36 columns of detailed description of the invention and the use of the well-known aspects of an MRI machine to perform the invention, Defendants initially took the position that all of the means plus function claims were indefinite for lack of a corresponding structure. As evidenced by the list of agreed terms, however, Defendants changed their position and now agree with NeuroGrafix that a number of the means-plus-function elements do indeed have disclosed corresponding structures. Weiss Decl. Ex. E at Exhibit at 15-16. As discussed below, because one of skill in the art would understand the extensive and detailed disclosure of the specification to clearly link structures to the recited functions for each of the means-plus-function terms, the terms can be construed and are not indefinite.

The means-plus-function analysis is a two-step analysis: "1) the court must first identify the function of the limitation; and 2) the court must then look to the

<sup>16</sup> During the meet and confer process, Defendants appeared to argue that this term was indefinite because it was claimed using functional language. This argument also has no merit. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1335 (Fed. Cir. 2009) ("functional language can be a claim limitation").

specification and identify the corresponding structure for that function." *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007) (citing *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1212 (Fed. Cir. 2003)). The corresponding structure must be clearly linked to the claimed function. *Med. Instrumentation*, 344 F.3d at 1211. The Federal Circuit has indicated that "[t]his is not a high bar" and only requires a disclosure in the specification such that one of ordinary skill in the art will know and understand the corresponding structure. *Biomedino*, 490 F.3d at 950.

**1. Claims 54(c), 64: Corresponding structures are not limited to performing blocks 112 through 154 in Figures 9 and 10.**

<u>NeuroGrafix's Construction</u>	<u>Defendants' Construction</u>
Claim 54(c) function: processing said outputs to generate data representative of the diffusion anisotropy of the selected structure	Claim 54 function: Processing said outputs to generate data representative of the diffusion anisotropy of the selected structure.
Corresponding Structures for Claim 54: 1. computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or 2. host processing system 32; and 3. their equivalents	Corresponding structure for claim 54: (1) computer 72 and front-end circuit 74, or host processing system 32, programmed to perform blocks 112 through 154 from Figures 9 and 10; and (2) equivalents thereof.
Claim 64 function: processing said data representative of the diffusion anisotropy of the selected structure to produce a data set that describes the shape and position of the selected structure	Claim 64 function: Processing said data representative of the diffusion anisotropy of the selected structure to produce a data set that describes the shape and position of the selected structure
Corresponding Structures for Claim 64: 1. computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or 2. host processing system 32; and 3. their equivalents	Corresponding structure for claim 64: (1) computer 72 and front-end circuit 74, or host processing system 32, programmed to perform blocks 112 through 154 from Figures 9 and 10 and further programmed to divide the output of the subtraction process by signal information from a fat suppressed, T2-weighted spin echo sequence; and (2) equivalents thereof.

1 The parties agree on the functions and that the specification discloses the  
2 functionality being performed by computer 72 and front-end circuit 74 or host  
3 processing system 32 and their equivalents. The parties disagree, however,  
4 regarding whether the corresponding structures must include an algorithm and, if  
5 so, the appropriate algorithm to include in the construction.

6 **a. Claim 54(c)**

7 **(1) The corresponding structure does not require a**  
8 **specific algorithm.**

9 A proper construction of this term does not require a specific algorithm  
10 because algorithms needed to perform those functions are readily apparent to a  
11 person of skill in the art. The parties agree that computer 72 and front-end circuit  
12 74 are the appropriate corresponding structure, but Defendants argue that a specific  
13 algorithm must also be included as corresponding structure. This is incorrect as a  
14 general rule and in this specific situation. In *In re Dossel*, 115 F.3d 942 (Fed. Cir.  
15 1997), the Federal Circuit addressed a patent in the medical imaging field and  
16 specifically two means-plus-function claim terms ("means for reconstructing the  
17 current distributions of the volume elements which are situated on said surfaces on  
18 the basis of said measured values" and "reconstruction means for determining the  
19 current distributions at said predetermined volume locations from said stored  
20 values"). 115 F.3d at 946. The Federal Circuit concluded that the structure  
21 underlying the functions recited in the *Dossel* claims was adequate to meet the  
22 requirements for definiteness in 35 U.S.C. § 112 ¶2, even though the "written  
23 description d[id] not disclose exactly what mathematical algorithm will be used to  
24 compute the end result" or use the "magic word 'computer'" but only "state[d] that  
25 'known algorithms' can be used to solve standard equations which are known in the  
26 art." *Id.* The Federal Circuit bolstered its opinion by noting that "in the medical  
27 imaging field, it is well within the realm of common experience that computers are  
28 used to generate images for display by mathematically processing digital input."  
*Id.* at 947. Accordingly, the claims in *Dossel* were not indefinite for lack of

disclosure of a specific algorithm, and logically any construction of the means-plus-function claim terms would not include a specific algorithm. *See id.*

The record here is even stronger than that in *Dossel*. First, there is agreement that the specification expressly discloses and clearly links to the function the structure of a processing system including a computer 72 and front-end circuit 74 as well as, alternatively, host processing system 32. Second, the function of claim 54 is processing the output "to generate data representative of the diffusion anisotropy of the selected structure." As opined by Dr. Filler, this functionality and the algorithms needed to perform it were well known within the art at the time. Weiss Decl. Ex. C at ¶75 (citing three contemporaneous articles). As Dr. Moseley, Defendants' expert, was one of the people using diffusion anisotropy in MRI machines at the time, he does not dispute that methods were known at the time of the invention to perform the recited functionality using a computer. *See* Weiss Decl. Ex. N at ¶¶ 17-25. Thus, no specific algorithm need be included in the construction. *See, e.g., In re Dossel*, 115 F.3d at 947.

(2) **Although unnecessary to include as part of the claim construction for claim 54(c), the '360 patent discloses and clearly links the recited function to an algorithm - blocks 112 through 148 of Figures 9 and 10.**

In any event, the specification of the '360 patent discloses an appropriate algorithm as shown in blocks 112 through 148 of Figures 9 and 10 of the '360 patent and the accompanying text, which describes acquiring and processing data representative of diffusion anisotropy. '360 patent at 14:32-18:22; *see also* Weiss Decl. Ex. C at ¶¶ 72, 75.<sup>17</sup> An algorithm can be expressed "in any understandable terms including as a mathematical formula, in prose...or as a flow chart, or in any other manner that provides sufficient structure." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008). The described algorithm, which

<sup>17</sup> Although Dr. Filler's report does not expressly refer to blocks 130 to 148, he does opine that the output must be processed for each diffusion-weighted gradient. Weiss Decl. Ex. C at ¶70. The disclosed algorithm for this functionality is shown in blocks 130 to 148 of Figure 10 of the '360 patent.

1 calculates diffusion coefficients, is an example of the recited functionality of  
2 element 54(c). *See* '360 patent at 18:30-33 ("These coefficients provide a measure,  
3 associated with each pixel or voxel, of the magnitude of diffusional anisotropy at  
4 that point, while the anisotropic direction is indicated by the gradient orientation.");  
5 *see also* Weiss Decl. Ex. C at ¶¶ 69-73.

6 Blocks 150 to 154 of Figure 10, which Defendants assert must also be  
7 included, relate to "Image Selection/Production," as indicated by the title of the  
8 section of the specification where the blocks are described, and are not necessary  
9 for the recited functionality "to generate data representative of the diffusion  
10 anisotropy of the selected structure." '360 patent at 18:23-46. The algorithm  
11 proceeds to block 150 only after computer 72 determines that it has completed  
12 generating the diffusion coefficients, which are data representative of diffusion  
13 anisotropy. *See* '360 patent at 18:24-33. Because the recited functionality of claim  
14 54(c) is satisfied prior to block 150, blocks 150, 152 and 154 are unnecessary for  
15 this functionality and should not be included in the construction.

16 **b. Claim 64: Although unnecessary to include as part of**  
17 **the claim construction for claim 64, the '360 patent**  
**discloses and clearly links the recited function to**  
**algorithms disclosed in the specification.**

18 The claim construction for the "processor means" of claim 64, like that for  
19 claim element 54(c) as explained above, does not require a specific algorithm. *See,*  
20 *e.g., In re Dossel*, 115 F.3d at 947. In any event, the recited function for claim 64  
21 is "processing said data representative of the diffusion anisotropy of the selected  
22 structure to produce a data set that describes the shape and position of the selected  
23 structure" and the specification discloses multiple algorithms that perform the  
24 functionality of processing the data "to produce a data set that describes the shape  
25 and position of the selected structure." As set out by Dr. Filler, the specification  
26 discloses that this function can be performed using subtraction according to block  
27 152 of Figure 10. '360 patent at 18:35-65, Figs. 15B-15D; *see also* Weiss Decl.  
28 Ex. C at ¶ 105. The specification also discloses that this function can be performed

RUSS, AUGUST & KABAT

using an algorithm for subtraction by dividing ('360 patent at 19:2-7) and a thresholding analysis instead of subtraction ('360 patent at 18:67-19:2). *See also* Weiss Decl. Ex. C at ¶ 105. In addition to the subtraction algorithms, the specification also discloses that various vector processing-related algorithms can be used as an algorithm to perform the recited functionality. '360 patent at 21:55-59 ("For example, the location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three-dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume."); 21:60-22:5 (alternative algorithm of tracking continuous serial changes in the direction of maximum anisotropy for the nerve); *see also* Weiss Decl. Ex. C at ¶ 111. As described below with respect to recited subfunctionality of claim 55(c), in spite of Dr. Moseley's opinion otherwise, the vector processing algorithms are also disclosed to one having skill in the art to be a corresponding algorithm for the recited functionality of claim 64. Each of these algorithms are described as alternatives to each other. Any one will do. *See Finisar*, 523 F.3d at 1341 (the patent need only "disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm to provide the necessary structure under § 112, P 6"). Thus, a proper construction includes all of the algorithms described in block 152 of Figure 10 and in the specification at 18:35-19:7 and 20:25-22:18 and their equivalents.

Defendants' proposed construction is too limiting because it only includes two of the three disclosed subtraction algorithms and does not include the disclosed vector processing algorithms. As a result, it should be rejected.

**2. Claim 55(c): Corresponding structures are computer 72 and front-end circuit 74 or host processing system 32 and their equivalents.**

<u>NeuroGrafix's Construction</u>	<u>Defendants' Construction</u>
Function: i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said	Function: i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

diffusion-weighted gradients with respect to the orientation of said selected structure; and ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy	diffusion-weighted gradients with respect to the orientation of said selected structure; and ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy.
Corresponding Structures: 1. computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or 2. host processing system 32; and 3. their equivalents	Corresponding structure: No corresponding structure disclosed, and term is not amenable to construction.

Although the parties agree on the recited functions for this term, the parties disagree about whether a corresponding structure has been recited in the specification. A person having ordinary skill in the art would have understood that the specification discloses and clearly links these recited functions to the corresponding structures of computer 72 and front-end circuit 74 or host processing system 32 and their equivalents. The recited functionality is actually two subfunctionalities: "i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion-weighted gradients with respect to the orientation of said selected structure;" and "ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy." Each subfunctionality is addressed separately below.

a. **Claim 55(c)(i): "vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion-weighted gradients with respect to the orientation of said selected structure"**

(1) **The corresponding structures for claim 55(c)(i) are computer 72 and front-end circuit 74 or host processing system 32 and their equivalents.**

The specification, in the view of one having ordinary skill in the art, clearly discloses the structure for the functionality recited in claim 55(c)(i). In the section entitled "Vector Processing and Three-Dimensional Image Generation," the specification discloses that "a technique has been developed for observing diffusional anisotropy, independent of its degree of alignment with any individual gradient axes." '360 patent at 20:26-28. The disclosed technique is "used to produce...directional information from the three orthogonal diffusion-weighted images described above." *Id.* at 20:33-35. The directional information, which is generated regardless of the alignment of the diffusion-weighted gradients with respect to the imaged structure, is the "data representative of anisotropic diffusion exhibited by a selected structure in the region" in claim 55(c)(i) functionality.<sup>18</sup> *See also* Weiss Decl. Ex. C at ¶ 85. The specification also discloses additional details and examples of claim 55(c)(i) functionality at 20:35-22:5.

The specification discloses and expressly links the function of claim 55(c)(i) to the structure of computer 72 and front-end circuit 74. "[T]he computer 72 is readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves between two-dimensional image planes or through a three-dimensional acquisition volume." '360 patent at 21:51-54. The specification recites that front-end circuit 74 is needed along with computer 72 because "[c]omputer 72 and front-end circuit 74 **cooperatively** control and synchronize the operation of the MRI system 14, as well as **process** and display **the acquired data**."

<sup>18</sup> "Said outputs" in claim 55(c)(i) refers to the "output indicative of the resonant response" from claim 55(b).

1 '360 patent at 11:11-14 (emphasis added). The specification also explains that the  
2 claim 55(c)(i) functionality requires "***faster processing speed***" ('360 patent at 20:26  
3 (emphasis added)), which further links claim 55(c)(i) functionality to computer 72  
4 and front-end circuit 74. One having ordinary skill in the art also knew that  
5 computer 72 and front-end circuit 74 were the standard processing structure used  
6 by MRI machines at the time. *See* Weiss Decl. Ex. C at ¶ 89.

7 The specification also discloses and expressly links host processing system  
8 32 to claim 55(c)(i) functionality by indicating that host processing system 32 can  
9 be used in place of computer 72 and front-end circuit 74:

10 "As one final component, medical system 12 may include a host processing  
11 system 32 in addition to, or in place of, separate processing systems in the  
12 other components of system 12."

13 '360 patent at 9:42-45.

14 Thus, the specification clearly links claim 55(c)(i) functionality to the  
15 disclosed corresponding structure of computer 72 and front-end circuit 74 or host  
16 processing system 74. *See* Weiss Decl. Ex. C at ¶¶ 87, 89-91.

17 **(2) The corresponding structure for claim 55(c)(i)  
18 does not require a specific algorithm.**

19 Similar to the "processor means" claim element 54(c) described above, the  
20 corresponding structure for "processor means" claim element 55(c)(i) does not  
21 require a specific algorithm. *See, e.g., In re Dossel*, 115 F.3d at 947. The  
22 specification provides some exemplary algorithms that could be used, such as  
23 those at 20:38-21:45, but then notes that "[s]uitable alternative processing  
24 techniques have been developed for use in the evaluation of magnetic, thermal, and  
25 structural anisotropy data." '360 patent at 21:45-47.

26 **(3) Although not required as part of the claim  
27 construction for claim 55(c)(i), the '360 patent  
28 discloses multiple algorithms for performing  
claim 55(c)(i) functionality.**

Although the construction of this claim limitation need not include a specific  
algorithm as part of the corresponding structure as discussed above, the

specification discloses multiple algorithms to perform claim 55(c)(i) functionality. *See* Weiss Decl. Ex. C at ¶ 88. For example, the specification discloses the use of three diffusion-weighted gradients and a normalizing zero diffusion gradient to produce a diffusion vector for each pixel. '360 patent at 20:36-46. The vector has a magnitude representative of image intensity and a direction representative of the "effective" diffusion gradient. *Id.* at 20:44-46. The specification goes on to recite specific equations to use to calculate this vector. *Id.* at 20:47-21:1. The disclosed information can then be used to produce "vector length" images (*see id.* at 21:1-15, Fig. 16) or "arctan images" (*see id.* at 21:16-23). A person having ordinary skill in the art understands these portions of the specification to disclose specific algorithms that can be run on the computer to perform claim 55(c)(i) functionality. *See* Weiss Decl. Ex. C at ¶ 88-89.<sup>19</sup>

The specification also describes additional algorithms that could be used to perform claim 55(c)(i) functionality. For example, the citation alone to Bassar et al., *Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal*, SMRM BOOK OF ABSTRACTS 1222 (1992) ('360 patent at 21:39-45) indicates algorithms that include tensor analysis. The articles also provide further consistent support regarding the knowledge of one of ordinary skill in the art in the 1992 time frame. A person having ordinary skill in the art understood that these were algorithms to perform claim 55(c)(i) functionality. *See* Weiss Decl. Ex. C at ¶ 88. Thus, if an algorithm is required as part of the corresponding structure for the computer of the "processing means," the proper construction includes the exemplary algorithms cited from 20:36 to 21:47 in the specification and their equivalents.

<sup>19</sup> Dr. Moseley also appears to agree that a person having ordinary skill in the art would understand that these are sufficient algorithms for the computer. Dr. Moseley fails to provide any opinion that contradicts Dr. Filler's opinion. *See* Weiss Decl. Ex. N at ¶¶40-44 (rebuttal expert report of Dr. Moseley).

b. **Claim 55(c)(ii): "processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy"**

(1) **The corresponding structures for claim 55(c)(ii) are computer 72 and front-end circuit 74 or host processing system 32 and their equivalents.**

The specification, in the view of one having ordinary skill in the art, clearly discloses and links structure to the claim 55(c)(ii) functionality: "computer 72 is readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves between two-dimensional image planes or through a three-dimensional acquisition volume." '360 patent at 21:51-54; *see also* Weiss Decl. Ex. C at ¶ 92. This "trac[ing] the course of the nerves" is one example of generating a data set describing the shape and position of the nerve in the region. Additionally, as the data was generated using diffusion-weighted gradients (*see* element (b) of claim 55), the resulting data will distinguish the nerve from other structures in the region that do not exhibit diffusion anisotropy.<sup>20</sup> *See, e.g.*, '360 patent at Figs. 16, 17 (images resulting from this functionality showing neural tracts distinguished from gray matter tissue of the brain that does not exhibit diffusion anisotropy); 5:3-39 (describing prior art use of diffusion-weighted gradients to distinguish anisotropic white matter tracks in the brain from isotropic matter although not able to detect the orientation of the neural tracts on a voxel by voxel basis).

The specification discloses and expressly links claim 55(c)(ii) functionality to computer 72 and front-end circuit 74. '360 patent at 21:51-54 ("The computer 72 is readily able..."). As discussed above, one having ordinary skill in the art, would have understood that the corresponding structure of claim 55(c)(ii) is computer 72 and front-end circuit 72 or host processing system 32 and their

<sup>20</sup> Structures that do not exhibit diffusion anisotropy include fat ('360 patent at 5:60-61 ("fat is isotropic")) and short T2 isotropically diffusing water ('360 patent at 28:36-37).

equivalents. *See* '360 patent at 11:11-14 ("[c]omputer 72 and front-end circuit 74 **cooperatively** control and synchronize the operation of the MRI system 14, as well as **process and display the acquired data.**" (emphasis added); 9:42-45 (host processing system 32 may encompass computer 72 and front-end circuit 74); *see also* Weiss Decl. Ex. C at ¶¶ 95-98. Thus, the specification clearly links claim 55(c)(ii) functionality to computer 72 and front-end circuit 74 or host processing system 74.

**(2) Although not required as part of the claim construction for claim 55(c)(ii), the '360 patent discloses multiple algorithms for performing claim 55(c)(ii) functionality.**

Although the construction of claim 55(c)(ii) need not require a specific algorithm as part of the corresponding structure as discussed above regarding claim 54(c), the specification discloses algorithms to perform claim 55(c)(ii) functionality. "For example, the location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three-dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume." '360 patent at 21:55-59. The specification also alternatively recites algorithms tracking continuous serial changes in the direction of maximum anisotropy for the nerve ('360 patent at 21:60-22:25). A person having ordinary skill in the art understands that this is an algorithm to generate a data set showing the shape and position of a nerve. *See* Weiss Decl. Ex. C at ¶ 93-94.<sup>21</sup> Thus, if an algorithm is required as part of the corresponding structure for the computer of the "processing means," the proper construction includes the exemplary algorithms described at 21:55-22:25 in the specification and their equivalents.

<sup>21</sup> Dr. Moseley attacks the recited exemplary examples from the specification as insufficient disclosure in his opinion but provides no support. Weiss Decl. Ex. N at ¶ 46-48. In addition, Dr. Moseley fails to address how one having ordinary skill in the art would understand the disclosure. As Dr. Filler opined, in his opinion, a person of ordinary skill understood the specification to include sufficient algorithms. *See* Weiss Decl. Ex. C at ¶¶ 93-94.

**3. Claims 58, 61: Corresponding structures are computer 72 and front-end circuit 74 or host processing system 32 and their equivalents.**

<b>NeuroGrafix's Construction</b>	<b>Defendants' Construction</b>
<p>Function: analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said analyzing the data representative of anisotropic diffusion, combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby [allowing]/[enabling] a three dimensional shape and position of curved [neural tissue]/[structure exhibiting anisotropic diffusion] to be described</p> <p>Corresponding Structures:</p> <ol style="list-style-type: none"> <li>1. computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or</li> <li>2. host processing system 32; and</li> <li>3. their equivalents</li> </ol>	<p>Function: To determine how to relate said data set and said additional data sets and to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby [enabling]/[allowing] [the]/[a] three dimensional shape and position of [curved neural tissue]/[a curved structure exhibiting anisotropic diffusion]/[curved structure exhibiting anisotropic diffusion] to be described.</p> <p>Corresponding structure: No corresponding structure disclosed, and term is not amenable to construction.</p>

The parties agree that, despite the variations in language, dependent claims 58 and 61 will have the same construction. These claims ultimately depend on claim 55. The recited functionality is "analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said analyzing the data representative of anisotropic diffusion, combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby [allowing]/[enabling] a three dimensional shape and position of curved [neural

tissue]/[structure exhibiting anisotropic diffusion] to be described."<sup>22</sup> This language is taken directly from the claims. Defendants' recited functionality ignores recited functionality language in the claims, such as that the processing means is "analyzing the data representative of anisotropic diffusion to determine..." and that the processing means is combining the data sets based on the results of the analyzing.

The specification, in the view of one having ordinary skill in the art, clearly discloses an example of the recited functionality:

computer 72 is readily able to identify nerve locations in the anatomical structure and to correctly trace the course of the nerves between two-dimensional image planes or through a three-dimensional acquisition volume. For example, the location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three-dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume.

'360 patent at 21:51-59; *see* Weiss Decl. Ex. C at ¶ 121. A person having ordinary skill in the art knows that the analysis of image intensity and linking of the results into a three-dimensional image is an example of the recited functionality. *See id.*<sup>23</sup>

The specification discloses and expressly links the recited functionality to computer 72 and front-end circuit 74 as the structure that performs the recited

<sup>22</sup> "Said additional data sets..." refers to the "additional data sets describing different cross sections..." in the preamble of claims 58 and 61. The specification discloses that cross sections are two-dimensional images, as illustrated by Figures 20, 21 and 23. *See also* '360 patent at 8:17-22, 8:26-28 (describing figures), 12:7 ("two-dimensional cross section"). The specification describes the data sets referenced in the recited functionality where, among other places, it notes that, until the functionality described in these claims and claim 55, "the output produced is generally in the form of a single two-dimensional image, or a series of two-dimensional images that can be related to form a three-dimensional image" with a high signal to noise ratio (in other words, low accuracy). '360 patent at 19:30-38; *see also, e.g.,* '360 patent at 20:35-45 (describing example with "four 'multislice' sets").

<sup>23</sup> An example of the recited functionality is also disclosed in the specification is the method of identifying the direction of maximum anisotropy and then using a voxel connection routine well known to one having ordinary skill in the art. '360 patent at 21:60-22:5.

1 functionality. '360 patent at 21:51-54 ("computer 72 is readily able..."). As  
2 discussed above, this disclosure, when viewed by one having ordinary skill in the  
3 art, would disclose a corresponding structure of computer 72 and front-end circuit  
4 72 or host processing system 32 and their equivalents. *See* '360 patent at 11:11-14  
5 ("[c]omputer 72 and front-end circuit 74 **cooperatively** control and synchronize the  
6 operation of the MRI system 14, as well as **process and display the acquired**  
7 **data.**" (emphasis added)); 9:42-45 (host processing system 32 may encompass  
8 computer 72 and front-end circuit 74); *see also* Weiss Decl. Ex. C at ¶¶ 95-98.  
9 Thus, the specification clearly links the recited functionality to computer 72 and  
10 front-end circuit 74 or host processing system 32.

11 Although the construction of claims 58 and 61 need not require a specific  
12 algorithm as part of the corresponding structure as discussed above regarding claim  
13 54(c), the specification discloses algorithms to perform the recited functionality.  
14 For example, claims 58 and 61 require analyzing and combining data to generate a  
15 further data set that allows a three dimensional shape and position of curved neural  
16 tissue or structure exhibiting anisotropic diffusion to be described, and an  
17 exemplary algorithm for performing this function is described as follows: "In a  
18 simple form of three-dimensional image generation, described in greater detail  
19 below, the high S/N ratio of the two-dimensional neurograms produced by system  
20 14 readily allows the imaged nerve cross-sections to be identified and then linked  
21 together to form a three-dimensional projection of the neural structure." '360  
22 patent at 19:33-38. *See also* '360 patent at 21:55-59 ("[T]he location of nerves in a  
23 given image plane can be detected by comparing pixel intensity to some threshold  
24 level. A three-dimensional image can then be formed by linking or projecting the  
25 results of these two-dimensional analyses over the desired volume."), 19:28-21:54,  
26 21:60-22:25. The specification also describes exemplary algorithms for tract  
27 tracing and tracing of nerves with three-dimensional imaging. '360 patent at 32:25-  
28 45, 33:33-45. A person having ordinary skill in the art understood that these

portions of the specification disclose algorithms to perform the functionality of claims 58 and 61. Thus, if an algorithm is required as part of the corresponding structure for the computer of the "processing means," the proper construction includes the exemplary algorithms cited at 19:33-38, 21:55-22:25, 32:25-45 and 33:33-45 in the specification and their equivalents.

**4. Claim 36(e): This term is not a step-plus-function element pursuant to Section 112 ¶6.**

<b>NeuroGrafix's Construction</b>	<b>Defendants' Construction</b>
This term is not step-plus-function element pursuant to Section 112 ¶6.	Governed by 112 ¶6 as a step-plus-function element, and is subject to the same construction as the second functionality for the "processor means" limitation in claim 55

Claim 36 is a method claim. Claim 36(e) recites:

"(e) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy."

Defendants contend that claim element 36(e) is a step-plus-function element governed by § 112 ¶6. Claim 36(e) is not governed by § 112 ¶6, because it lacks the "steps for" form and includes the presence of an act in the claim language.

Similar to means-plus-function claims, where a claim term does not use the "step-for" formulation, the presumption is that the claim term is not a step-plus-function term under § 112 ¶6. *Masco Corp. v. U.S.*, 303 F.3d 1316, 1326 (Fed. Cir. 2002). "Where the claim drafter has not signaled his intent to invoke § 112, paragraph 6 by using the 'steps for' language," the Federal Circuit has been "unwilling to resort to that provision to constrain the scope of coverage of a claim limitation without a showing that the limitation contains nothing that can be construed as an act." *Id.* at 1327.

Each claim term alleged to be a step-plus-function element subject to 35

RUSS, AUGUST & KABAT

U.S.C. § 112 ¶6 must be reviewed independently. *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997). Merely using the same language that is functional language in a means-plus-function element does not make it a step-plus-function element. *Id.* at 1582-83 ("Interpretation of claims would be confusing indeed if claims that are not means- or step-plus-function claims were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.").

"If an act is present, then the limitation is not a step plus function." *Masco*, 303 F.3d at 1327. This standard has been applied very broadly. For example, the Federal Circuit has overturned a district court for holding "determining a condition of the heart from among a plurality of conditions of the heart" as a step-plus-function claim. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371, 1381-82 (Fed. Cir. 2004). Similarly, Judge Ware has rejected arguments that the element "storing, as a file, the compressed, formatted and sequenced data blocks with the assigned unique identification code" is a step-plus-function claim. *Acacia Media Techs. Corp. v. New Destiny Internet Group*, Case No. CV 02-1040-JW(MLGx), 2004 U.S. Dist. LEXIS 13415, at \*48-49 (C.D. Cal. Jul. 12, 2004) .

Here, claim 36(e) does not include the "steps for" language, and it recites the act of "processing said data." It is thus not subject to 112 ¶6. *See, e.g., Masco*, 303 F.3d at 1327; *Cardiac Pacemakers*, 381 F.3d at 1381-82.

Defendants' argument is premised on the fact that the language used in claim 36, element (e) is the very similar as the functional language used in claim 55, element (c). The Federal Circuit has, however, rejected this very argument. *O.I. Corp.*, 115 F.3d at 1582-83. Claim 36(e) is not a step-plus-function element.

**5. Claims 39, 46, 49: This term is not a step-plus-function element pursuant to Section 112 ¶6.**

<b>NeuroGrafix's Construction</b>	<b>Defendants' Construction</b>
This term is not step-plus-function element pursuant to Section 112 ¶6.	Governed by 112 ¶6 as a step-plus-function element, and is subject to the same construction as the second functionality for the "processor

means" limitation in claims 58 and 61

Claims 39, 46 and 49 are all dependent method claims, and all recite similar functionality of "analyzing the data..." and "combining said data..." The parties agree that the construction of all of these claims will be the same. Just as with the preceding term, this term is not a step-plus-function element. It lacks the "steps for" language and discloses the acts of analyzing and combining. Also just as above, Defendants argument based on the similarity in language between this term and the mean-plus-function language in claims 58 and 61 has already been rejected by the Federal Circuit. *O.I. Corp.*, 115 F.3d at 1582-83. This term is therefore not subject to 35 U.S.C. 112 ¶6. *See, e.g., Masco*, 303 F.3d at 1327; *Cardiac Pacemakers*, 381 F.3d at 1381-82.

## VI. CONCLUSION.

This Court should adopt NeuroGrafix's proposed constructions because they are consistent with the intrinsic evidence when read by one having ordinary skill in the art. Defendants' proposed constructions are unsupported by law and the intrinsic evidence and should therefore be rejected.

Dated: February 11, 2011

Respectfully submitted,

**RUSS, AUGUST & KABAT**

By: /s/ Andrew D. Weiss  
Andrew D. Weiss

**Attorneys for Plaintiff  
NEUROGRAFIX**

**K&L GATES**

By: /s/ David T. McDonald (by permission)  
David T. McDonald

**Attorneys for Plaintiff  
WASHINGTON RESEARCH FOUNDATION**

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on February 11, 2011. Any other counsel of record will be served via First Class U.S. Mail on this same date.

By: /s/ Andrew D. Weiss  
Andrew D. Weiss

RUSS, AUGUST & KABAT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28